

Serial No. 10/775,964

Claim Listing:

1-33. (Canceled)

34. (Currently Amended) A method of producing a microparticle composition, said method comprising:

(a) forming an emulsion comprising (i) a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate, (ii) an organic solvent, (iii) a detergent and (iv) water; and

(b) removing the organic solvent from the emulsion to form microparticles;

wherein said microparticles are subjected to a filtration step such that wherein about 10-90% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound, and-or wherein said microparticles are not subjected to a washing step and the ratio of the detergent to the polymer ratio is selected such that about 10-90% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.

35. (Previously presented) The method of claim 34, wherein the emulsion is a water-in-oil-in-water emulsion that is formed by a process comprising:

(a) emulsifying an organic phase comprising the polymer and the organic solvent with a first aqueous phase comprising water to form a water-in-oil emulsion; and

(b) emulsifying a second aqueous phase comprising the detergent and water with the emulsion formed in step (a) to form a water-in-oil-in-water emulsion.

36. (Original) The method of claim 34, wherein a cross-flow filtration step is performed after removing the organic solvent.

37. (Currently Amended) A method of producing a microparticle composition, said method comprising:

Serial No. 10/775,964

(a) forming an emulsion comprising (i) a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate, (ii) an organic solvent, (iii) a cationic detergent and (iv) water, wherein the cationic detergent is provided in the emulsion at a weight to weight detergent to polymer ratio of from about 0.05:1 to about 0.5:1; and

(b) removing the organic solvent from the emulsion to form microparticles; wherein said microparticles are subjected to a filtration step such that about 10-90% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound, ~~and wherein said microparticles are not subjected to a washing step.~~

38. (Original) The method of claim 37, wherein the cationic detergent is provided in the emulsion at a weight to weight detergent to polymer ratio of from about 0.1:1 to about 0.5:1, wherein the polymer is poly(D,L-lactide-co-glycolide), and wherein the cationic detergent is CTAB.

39. (Currently Amended) A method of producing a microparticle composition, said method comprising:

(a) forming an emulsion comprising (i) a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate, (ii) an organic solvent, (iii) a cationic detergent and (iv) water, wherein the cationic detergent is provided in the emulsion at a weight to weight detergent to polymer ratio of from about 0.001:1 to about 0.05:1; and

(b) removing the organic solvent from the emulsion to form microparticles; wherein said microparticles are not subjected to a washing step and the ratio of the detergent to the polymer ratio is selected such that about 10-90% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound, ~~and wherein said microparticles are not subjected to a washing step.~~

Serial No. 10/775,964

40. (Original) The method of claim 39, wherein the cationic detergent is provided in the emulsion at a weight to weight detergent to polymer ratio of from about 0.002:1 to about 0.04:1, wherein the cationic detergent is CTAB, wherein the polymer is poly(D,L-lactide-co-glycolide), and wherein the microparticles are not subjected to a step to remove excess CTAB from the composition.

41. (Original) The method of claim 34, wherein the polymer is a poly(D,L-lactide-co-glycolide) having a lactide/glycolide molar ratio ranging from 40:60 to 60:40 and a molecular weight ranging from 30,000 Daltons to 70,000 Daltons.

42. (Original) A microparticle composition formed by the process of claim 34.

43. (Currently amended) A method of producing a biologically active microparticle composition, said method comprising:

- (a) providing ~~an unwashed~~ a microparticle composition produced by the method of claim 34; and
- (b) incubating the unwashed microparticle composition with a biologically active macromolecule.

44. (Original) The method of claim 43, wherein the biologically active macromolecule is a polynucleotide.

45-57. (Canceled)

58. (Currently amended) A method of producing a biologically active microparticle composition, said method comprising:

- (a) providing ~~an unwashed~~ a microparticle composition produced by the method of claim 37; and
- (b) incubating the unwashed microparticle composition with a biologically active macromolecule.

Serial No. 10/775,964

59. (Previously presented) The method of claim 58, wherein the biologically active macromolecule is a polynucleotide.

60. (Previously presented) A method of producing a biologically active microparticle composition, said method comprising:

- (a) providing an unwashed microparticle composition produced by the method of claim 39; and
- (b) incubating the unwashed microparticle composition with a biologically active macromolecule.

61. (Previously presented) The method of claim 60, wherein the biologically active macromolecule is a polynucleotide.

62. (New) The method of claim 34, wherein about 10-60% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.

63. (New) The method of claim 34, wherein about 25-40% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.

64. (New) The method of claim 37, wherein about 10-60% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.

65. (New) The method of claim 37, wherein about 25-40% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.

Serial No. 10/775,964

66. (New) The method of claim 39, wherein about 10-60% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.

67. (New) The method of claim 34, wherein about 25-40% of the total detergent in the microparticle composition is bound to the microparticles and the remainder is unbound.